

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

This document relates to:
*The Government of Puerto Rico v. Teva
Pharmaceutical Industries, Ltd. et al.,
Case No. 1:22-op-45007*

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

**THE GOVERNMENT OF PUERTO RICO’S MEMORANDUM OF LAW
IN SUPPORT OF RENEWED MOTION TO REMAND AND FOR EXPEDITED
BRIEFING SCHEDULE**

Plaintiff, the Government of Puerto Rico (“the Government” or “Puerto Rico”) respectfully submits this Memorandum in Support of Renewed Motion to Remand this case back to the Puerto Rico Superior Court. The Government of Puerto Rico sued the Defendants, all of whom are entities in the Teva and Allergan/Actavis corporate families, in San Juan Superior Court, where this action belongs. The Complaint asserts four causes of action, all of which are based exclusively on Puerto Rico law. Notwithstanding the absence of a federal claim, Actavis Laboratories FL (the “Removing Defendant” or “Actavis”) improperly removed the case to the U.S. District Court for the District of Puerto Rico, purporting to invoke the Court’s federal question jurisdiction under 28 U.S.C. § 1331.

The removal is a transparent attempt at delay, and one that for months has succeeded as the Government awaited a decision following remand briefing and the case transferred to the MDL before such a decision could issue. The Removing Defendant is also a defendant in this MDL and should be aware that this Court rejected precisely the same unfounded removal argument when asserted by Walgreens in a case by the Commonwealth of Kentucky. *See Commonwealth of*

Kentucky et al. v. Walgreens Boots Alliance, Inc. et al., No. 1:18-op-46311, Dkt. 13 (N.D. Ohio Jan. 14, 2019), *later withdrawn as moot*, *See Commonwealth of Kentucky et al. v. Walgreens Boots Alliance, Inc. et al.*, No. 1:18-op-46311, Dkt. 15 (N.D. Ohio Jan. 17, 2019); *see also In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 Dkt. 899 (N.D. Ohio Aug. 23, 2018) (remanding action by Montana against opioid manufacturer). This Court consistently has recognized the right of Attorneys General to pursue their own actions in their jurisdiction's courts and further admonished that it "has already recognized that **it has no jurisdiction over state cases filed by state attorneys general.**" *In re: National Prescription Opiate Litig.*, MDL 2804, 2019 WL 180246 at *2 (N.D. Ohio Jan. 14, 2019) (emphasis added); *see also* MDL 2804 Doc. 94 (January 24, 2018 Order).¹

This case is no exception. Indeed, the removal is curious because cases are proceeding against various Actavis entities, who share common counsel, in state courts in Ohio, West Virginia, Kentucky, Rhode Island, Florida, Georgia, Illinois, Hawaii, Mississippi, Louisiana, Alaska, and Nevada. Actavis Laboratories FL was named as a defendant in a case by the State of Alaska as recently as last spring, yet made no attempt to remove that case. Its singling out of Puerto Rico is inexplicable. Further, consistent with this Court's prior rulings is an expansive body of authority from courts around the country that have rejected the same arguments asserted here. *See, e.g.*, Order, *Oklahoma, ex rel., Hunter v. Purdue Pharma L.P.*, No. 5:18-cv-00574-M (W.D. Okla. Aug. 3, 2018), ECF No. 53 (attached as **Ex. A**); *New Mexico, ex rel. Balderas v. Purdue Pharma L.P.*, 323 F. Supp. 3d 1242 (D.N.M. June 12, 2018); *Delaware, ex rel. Denn, Att'y Gen. v. Purdue Pharma L.P.*, 2018 WL 1942363 (D. Del. Apr. 25, 2018); Mem. Op. & Order, *West Virginia v.*

¹ The MDL Court uniformly has remanded all Attorney General actions transferred to the MDL. The lone exception is the State of Idaho's AG-led case, which the Idaho Attorney General chose to file in federal court in the first place. The State of Alabama also filed its AG-led case originally in federal court, but thereafter voluntarily dismissed it, after the MDL court questioned its jurisdiction over the case.

McKesson Corp., No. 2:17-cv-03555 (S.D.W. Va. Feb. 15, 2018), ECF No. 21 (attached as **Ex. B**); *West Virginia ex rel. Morrissey v. McKesson Corp.*, 2017 WL 357307 (S.D.W. Va. Jan. 24, 2017); *Fayetteville Ark. Hosp. Co. v. Amneal Pharms., LLC*, 2020 WL 2521515, at *2 (W.D. Ark. May 18, 2020); *Cnty. of Kern v. Purdue Pharma L.P.*, 2019 WL 3310668 (E.D. Cal. July 23, 2019) (attached as **Ex. C**); *City of El Monte v. Purdue Pharma L.P.*, No. 2:19-cv-03588-JFW-PLA (C.D. Cal. June 18, 2019), ECF No. 38 (attached as **Ex. D**); *Dinwiddie Cnty., Va. v. Purdue Pharma, L.P.*, 2019 WL 2518130 (E.D. Va. June 18, 2019); *Dunaway v. Purdue Pharma L.P.*, 2019 WL 2211670 (M.D. Tenn. May 22, 2019); Mem. Op. & Order, *Cnty. Bd. of Arlington Cnty. v. Purdue Pharma, L.P.*, No. 1:19-cv-00402 (E.D. Va. May 6, 2019), ECF No. 63 (attached as **Ex. E**); Order on Mot. to Remand & Mot. to Stay, *City of Boston v. Purdue Pharma L.P.*, No. 1:18-cv-12174 (D. Mass. Jan. 29, 2019), ECF No. 32 (attached as **Ex. F**); *Tucson Med. Ctr. v. Purdue Pharma LP*, 2018 WL 6629659 (D. Ariz. Dec. 19, 2018); *City of Reno v. Purdue Pharma, L.P.*, 2018 WL 5730158 (D. Nev. Nov. 2, 2018); Order, *Cnty. of Anderson v. Rite Aid of S.C., Inc.*, No. 8:18-cv-01947 (D.S.C. Aug. 20, 2018), ECF No. 44 (attached as **Ex. G**); *Weber Cnty. v. Purdue Pharma, L.P.*, 2018 WL 3747846 (D. Utah Aug. 7, 2018); *Uintah Cnty. v. Purdue Pharma, L.P.*, 2018 WL 3747847 (D. Utah Aug. 7, 2018); *City of Granite City v. AmerisourceBergen Drug Corp.*, 2018 WL 3408126 (S.D. Ill. July 13, 2018); *see also In re Nat'l Prescription Opiate Litig.*, MDL 2804, 2018 WL 4019413 (N.D. Ohio Aug. 23, 2018).

As set forth below, Actavis, like the defendants in the above-mentioned actions, simply mischaracterizes the Government's claims. There is no federal jurisdiction here. *First*, under the well-pleaded complaint rule, to confer subject matter jurisdiction, the complaint must raise a federal question. Here, the Government pled claims exclusively under Puerto Rico law.

Second, Actavis cannot carry its burden of showing that the Government’s state law claims could have been brought in federal court under the test set forth in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing*, 545 U.S. 308 (2005), and *Gunn v. Minton*, 568 U.S. 251 (2013). As noted above, courts have repeatedly found that the federal issue identified by the Removing Defendant was “not necessarily raised, substantial, or possible to entertain without disrupting the congressionally-approved balance between state and federal courts,” and thus rejected arguments that allegations concerning claimed violations of the Controlled Substances Act (“CSA”), 21 U.S.C. § 801 *et seq.*, provide a basis for federal jurisdiction. 2018 WL 1942363, *2-5 (D. Del. Apr. 25, 2018); *see also, e.g., Balderas*, 323 F. Supp. 3d at 1250-53; *West Virginia*, No. 2:17-cv-03555, ECF No. 21 at 3 & 13-14.

Such allegations are “insufficiently ‘substantial’ to confer federal-question jurisdiction.” *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 814 (1986). Further, allowing removal of state law claims such as this, which are routinely tried in state court, would upset the state-federal jurisdictional balance. As explained further below, when federal jurisdiction is doubtful, federal courts must remand the case to state court. *Maryland Stadium Authority v. Ellerbe Becket Inc.*, 407 F.3d 255, 260 (4th Cir. 2005). Where, as here, a State’s Attorney General brings an action, principles of federalism are of additional, greater import. *Pennsylvania v. Eli Lilly & Co., Inc.*, 511 F. Supp. 2d 576, 586 (E.D. Pa. 2007). Lastly, Removal of the Government’s case would “disturb[] any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314.

For the reasons set forth below, the Government respectfully requests that the Court direct expedited briefing and promptly remand this case back to Puerto Rico Superior Court.

I. BACKGROUND

On August 27, 2021, the Government of Puerto Rico sued the Defendants in San Juan Superior Court. The Complaint asserts four causes of action, all of which are based exclusively on Puerto Rico law: statutory public nuisance (§§ 201-219); statutory negligence/fault (Article 1802 of the Puerto Rico Civil Code) (§§ 220-240); violations of the Puerto Rico Fair Competition Act (§§ 241-252); and unjust enrichment (§§ 253-262).² The Complaint alleges that the Defendants are responsible for creating and maintain a public nuisance in Puerto Rico, violated Puerto Rico statutes, and are subject to an unjust enrichment claim due to their misconduct in deceptively marketing opioids and flooding Puerto Rican communities with these dangerous drugs, instead of adhering to effective controls and conducting due diligence to guard against diversion of these dangerous drugs, fueling an illicit market in these drugs that predictably developed and that Defendants helped create, expand, and maintain. *See generally The Government of Puerto Rico v. Teva Pharmaceuticals LTD, Inc., et al.*, SJ-2021-CV-05540 (Super. Ct. Aug. 27, 2021). Puerto Rico’s Complaint does not allege that every order was suspicious. *See id.* The complaint does not purport to assert a cause of action under the CSA, nor does it make, for example, allegations that the Defendants failed to “report[] that the total volume of prescription opioids was unreasonable,” Dkt. No. 1 at 9 n.3, or challenge any Drug Enforcement Administration (“DEA”) quota, as the Removing Defendant oddly suggests.

Actavis removed the case on November 11, 2021, Dkt. No. 1, and the Government moved to remand, Dkt. No 9. Before a decision could issue, on February 1, 2022, the Judicial Panel on Multidistrict Litigation (“JPML”) transferred the action to this Court. *See* Dkt. No. 25.

² References to “¶ _” are to paragraphs of the Complaint, Dkt. _.

II. LEGAL STANDARD

It is axiomatic that the federal courts are “courts of limited jurisdiction. They possess only that power authorized by Constitution and statute.” *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005) (internal quotation omitted). This rule embodies the “due regard for the rightful independence of state governments, which should actuate federal courts, [by requiring] that they scrupulously confine their own jurisdiction to the precise limits which the statute has defined.” *Exec. Jet Aviation, Inc. v. Cleveland*, 409 U.S. 249, 272-73 (1972) (internal quotation omitted). The burden of establishing federal jurisdiction falls to the party invoking the removal statute. *See, e.g., Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 549 (6th Cir. 2006).

Because removal jurisdiction raises significant federalism concerns, federal courts must construe removal statutes strictly. *Shamrock Oil & Gas Corp. v. Sheets*, 313 U.S. 100 (1941); *Mays v. City of Flint, Mich.*, 871 F.3d 437, 442 (6th Cir. 2017). Whenever federal jurisdiction is doubtful, federal courts must remand the case to state court. *Maryland Stadium Authority v. Ellerbe Becket Inc.*, 407 F.3d 255, 260 (4th Cir. 2005). Further, when a State’s Attorney General brings an action, principles of federalism are of additional, greater import. *Pennsylvania v. Eli Lilly & Co., Inc.*, 511 F. Supp. 2d 576, 586 (E.D. Pa. 2007). As the United States Supreme Court has noted, “considerations of comity make us reluctant to snatch *cases which a State has brought* from the courts of that State, unless some clear rule demands it.” *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 21 n.22 (1983) (emphasis added).

III. ARGUMENT

A. FEDERAL LAW DOES NOT CREATE THE CAUSES OF ACTIONS IN THIS CASE.

Under long-settled precedent, federal question jurisdiction can only exist when a plaintiff’s complaint raises significant question of federal law. A federal question raised by an anticipated defense is not sufficient to confer jurisdiction. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392-

393 (1987); *see also In re Nat'l Prescription Opiate Litig.*, 2019 WL 180246, at *1 (vacated as moot) (remanding action that “does not facially assert federal-law claims”).

Here, there is no federal jurisdiction because the Government relies exclusively on state law for their claims. While a violation of the federal CSA may well constitute evidence of one or more of the Government’s causes of action under Puerto Rico law, proof of such a federal law violation is not an “essential element” of any of the claims. *See Gully v. First Nat’l Bank in Meridian*, 299 U.S. 109, 112 (1936). To confer “arising-under” jurisdiction, “a right or immunity created by the Constitution or laws of the United States must be an element, **and an essential one**, of the plaintiff’s cause of action.” *Id.* (emphasis added).

Moreover, as the Removing Defendant acknowledges, “the CSA does not provide for a private right of action.” Dkt. 1, ¶ 33. That is, Congress has expressed its intent that these cases not be litigated in federal court. Here, because there is no private right of action to enforce the CSA, “there is no indication of legislative intent to create a federal cause of action displacing traditional state law . . . causes of action.” *Great Lakes Gas Transmission Ltd. P’ship v. Essar Steel Minn. LLC*, 843 F.3d 325, 331 (2016). The Supreme Court’s ruling in *Merrell Dow Pharms. Inc. v. Thompson*, 478 U.S. 804, 814 (1986) is instructive. There, plaintiffs brought state common law causes of action against the manufacturer of Bendectin. Plaintiffs alleged, *inter alia*, that Merrell Dow’s violation of the misbranding provisions of the federal Food, Drug, and Cosmetic Act (“FDCA”) gave rise to a rebuttable presumption of negligence under state law. The Supreme Court nevertheless found no basis for federal question jurisdiction. *See Merrell Dow*, 478 U.S. at 814 (“We simply conclude that the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently

‘substantial’ to confer federal-question jurisdiction.”); *accord e.g. Florida Health Scis. Ctr., Inc. v. Sackler*, 19-62992-CIV, 2020 WL 1046601, at *2–4 (S.D. Fla. Jan. 24, 2020)³

In similar opioid litigation, Courts rejecting the same arguments the Removing Defendant makes in its removal notice also have found that the absence of a private cause of action under the CSA weighed heavily in favor of remanding the case. *See, e.g., Balderas*, 323 F. Supp. 3d at 1250-53; 2018 WL 1942363, *2-5 (D. Del. Apr. 25, 2018); *West Virginia*, No. 2:17-cv-03555, ECF No. 21 at 3 & 13-14.

B. THIS CASE DOES NOT “NECESSARILY RAISE” A “SUBSTANTIAL” FEDERAL QUESTION SUFFICIENT TO CONFER FEDERAL JURISDICTION UNDER *GRABLE*

The Removing Defendant’s removal notice seeks to invoke the narrow exception recognized by the Supreme Court in *Grable* for a “special and small category of cases” in which “federal-question jurisdiction will lie over state-law claims that implicate significant federal issues.” 545 U.S. at 312. Plainly, this case falls outside that narrow exception.

i. Failure to Identify Any Federal Issue “Necessarily Raised” and “Actually Disputed”

As the Removing Defendant tacitly acknowledges in its removal notice, the Government can prove its case simply by proving the elements of its state law causes of action. *See* Dkt. 1 at 11 (acknowledging that the Government expressly pled state law claims). To the extent that the paragraphs in the Complaint reference CSA violations, they also include allegations that Defendants had duties under Puerto Rico law to, among other things, report and halt suspicious

³ As the Supreme Court subsequently explained, the decision in *Merrell Dow* was also motivated by a concern that recognition of federal question jurisdiction under these circumstances would disturb the balance of federal and state judicial responsibilities approved by Congress. *See Grable*, 545 U.S. at 318 (“[I]f the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.”); *see also Great Lakes*, 843 F.3d at 331 (“Because federal law does not create the cause of action identified in the FAC, federal question jurisdiction may not rest on this basis.”).

orders and maintain effective controls against diversion. For example, the Government’s public nuisance claim identifies Puerto Rico law as the basis for this claim (§§ 201-219); the negligence/fault claim is also a Puerto Rico law claim (§§ 220-240); violations of the Fair Competition Act are exclusive to Puerto Rico law (§§ 241-252); and the unjust enrichment claim is based on Puerto Rico law as well (§§ 253-262.) It is clear that each of the four claims of the Complaint is not only predicated on Puerto Rico law, but that to the extent a statutory standard is referenced, the claims may be established based on violations of state law duties. *See Pressl v. Appalachian Power Co.*, 842 F.3d 299, 304 (4th Cir. 2016) (“[A] claim ‘necessarily depends on a question of federal law only when every legal theory supporting the claim requires the resolution of a federal issue.’”).

Furthermore, even when state laws parallel or integrate federal standards or statutes, they do not justify federal jurisdiction. This Court recognized as much in remanding Montana’s action. *See* MDL Dkt. 899 at 3 (“the mere presence of a federal issue in a state law claim” does not automatically confer federal question jurisdiction”) (quoting *Merrell Dow*). Although Walgreens abandoned its removal efforts, prompting this Court to vacate its decision as moot, this Court too previously rejected the same arguments Actavis makes here, stating:

District Courts examining virtually identical facts to those present here have determined that:

“While a determination of a duty and violation of that duty under the FCSA will likely occur in examining Plaintiff’s claims, so also will examination of [state] common law, statutes, and promulgated rules to determine Defendants’ duty, if any, to prevent ‘diversion’ of prescription drugs into illicit channels. And to the extent, if any, that Plaintiff’s claims are partially predicated on federal law, federal law would still not be necessarily raised.”

In re Nat’l Prescription Opiate Litig., 2019 WL 180246, at *2 (vacated as moot) (quoting *Balderas*, 323 F. Supp. 3d at 1252) (internal quotation marks omitted). As this Court rightly observed, it remains true that, under identical circumstances in other opioid litigation, courts uniformly have

found that the federal issue of whether a defendant violated its obligations under the federal CSA was not “necessarily raised.” In *Denn*, the Delaware court reasoned:

Although a determination of whether Defendants violated the FCSA may occur while addressing Plaintiff’s claims, there is also the possibility that the claims will be resolved without resolution of the federal issue at all. Based on the complaint, it is possible for the state law claims to be resolved solely under state law. Although the complaint addresses some duties or requirements under the FCSA, the complaint also lists several other duties and standards that arise solely under state statutory or common law.

2018 WL 1942363, at *2 (citation omitted). In particular, the Delaware court concluded that the state could prevail on its Delaware Consumer Fraud Act claim based on alleged misrepresentations “unrelated to federal law,” on its public nuisance claim “by showing Defendants violated the Delaware Controlled Substances Act,” and on its negligence claim by showing conduct that fell below standards of care that did not reference federal law. *Id.* at *3.

The *Balderas* court engaged in an identical analysis:

[C]ontrary to McKesson’s claim that Plaintiff can prevail only by showing that Defendants violated the FCSA, it appears that Plaintiff could show that Defendants violated state law duties to control, report and guard against the diversion of prescription drug orders, meaning that the federal statute is not necessarily raised. While a determination of a duty and violation of that duty under the FCSA will likely occur in examining Plaintiff’s claims, so also will examination of New Mexico common law, statutes, and promulgated rules to determine Defendants’ duty, if any, to prevent “diversion” of prescription drugs into illicit channels. . . . New Mexico state law provides alternate theories for a finding of liability against McKesson and its codefendants because the Complaint implicates numerous alleged duties under state law. Thus, as in *Merrell Dow*, the Complaint refers to the FCSA, its reg-

ulations, and the DEA letters as “available criter[ia] for determining whether” Defendants are liable, but their liability, if any, does not hinge *exclusively* on federal law, as McKesson argues.

323 F. Supp. 3d at 1252 (citations omitted) (rejecting arguments based on contentions that “manufacturing quotas and duties regarding reporting and shipping suspicious opioid orders arise ‘solely’” under federal law).⁴

Likewise here, because the Defendants may be found liable on the Government’s claims based on allegations that do not require violations of federal law, no federal issue is “necessarily raised” under the first prong of the *Grable* test.⁵

ii. Failure to Identify a Disputed Federal Issue, Much Less a “Substantial” One

Moreover, *Grable* jurisdiction is reserved for almost pure questions of law, such as the interpretation of the IRS notice requirement at issue in that case. By contrast, “[n]o substantial federal issue will be found where a claim is ‘fact-bound and situation-specific.’” *McKay v. City & Cnty. of S.F.*, 2016 WL 7425927, at *4 (N.D. Cal. Dec. 23, 2016) (quoting *Empire HealthChoice*

⁴ See also *West Virginia*, No. 2:17-cv-03555, ECF No. 21 at 12 (“The earlier remand decision focused extensively on whether the alleged federal issue was necessarily raised and Judge Copenhaver rightly concluded that it was not.”); *Morrissey*, 2017 WL 357307, at *4-8; *accord Oklahoma*, No. 5:18-cv-00574, ECF No. 53 (applying *Grable* and finding that a federal question was not necessarily raised, such that it was unnecessary to consider the remaining factors and remanding case removed by an opioid manufacturer); *In re Nat’l Prescription Opiate Litig.*, 2018 WL 4019413, at *3 (concluding that “no federal issue [wa]s necessarily raised” in the State of Montana’s lawsuit against Purdue Pharma, *et al.*, and noting that the plaintiff was in no way asking the court to second guess the validity of the Food and Drug Administration’s drug-labeling or decision-making); see also *Weber Cnty.*, 2018 WL 3747846, at *6 (“McKesson fails to identify a specific provision in the CSA which will require interpretation or construction by any court.”).

⁵ These decisions are fully consistent with authority outside the opioid context as well. Even if the Complaint relies on state law that incorporates federal requirements, as opposed to including the independent duties also cited, a federal question still would not be necessarily raised. See *Bueth v. Britt Airlines, Inc.*, 749 F.2d 1235, 1239 (7th Cir. 1984) (“[A] claim does not arise under federal law merely because a state law incorporates federal law by reference.”); *Nuclear Eng’g Co. v. Scott*, 660 F.2d 241, 249 (7th Cir. 1981) (“[S]tate law incorporation of federal law does not fairly allow . . . state law claims to be construed as essentially federal in character.”); see also *Wander v. Kaus*, 304 F.3d 856, 858-59 (9th Cir. 2002) (finding state law claim based on violation of federal Americans with Disabilities Act did not give rise to federal question jurisdiction and describing issue as “materially indistinguishable from *Merrell Dow*”); *Caggiano v. Pfizer, Inc.*, 384 F. Supp. 2d 689, 691 (S.D.N.Y. 2005) (granting remand when “federal standards merely inform the content of classically state-law duties such as avoiding negligence and fraud”).

v. McVeigh, 547 U.S. at 700 (2006)); *see also Great Lakes*, 843 F.3d at 332 (“[T]here is little national interest in having a federal court interpret . . . provisions if it will merely apply state law.”).

Here, it is hard to imagine a more fact-bound inquiry than the Removal Defendant’s dispute over whether it violated state law standards of care. Even assuming a federal question were necessarily presented, “[t]he [Supreme] Court has cautioned that it takes more than a federal element to open the arising under door.” *West Virginia*, No. 2:17-cv-03555, ECF No. 21 at 9 (internal quotation marks omitted). Here, the Removal Defendant’s arguments are precisely the kind of fact-bound disputes (resting on a mischaracterization of the Complaint) that caution against removal. *See, e.g., Weber Cnty.*, 2018 WL 3747846, at *8 (“[O]n their face, the issues McKesson recites appear ‘fact bound’ and ‘situation specific,’ auguring against federal jurisdiction.”); *Cnty. of Anderson*, No. 8:18-cv-01947, ECF No. 44 at 20 (“[D]etermination of the Distributor Defendants’ compliance with their putative duties to detect, report, and stop shipment of ‘suspicious orders,’ as defined in the federal regulations, is necessarily fraught with ‘fact-bound and situation-specific’ inquiries, favoring a finding against substantiality.”).

The scope of the duties of distributors and dispensers of opioids under the CSA has long been clear. The decision in *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017), conclusively resolved any challenge to the interpretation of that law. Further, the requirements at issue have been well-established for years. *See Southwood Pharms., Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007); 21 U.S.C. § 823; 21 C.F.R. 1301.74. *See also In re Nat’l Prescription Opiate Litig.*, MDL 2804, 2019 WL 3917575, at *1 (N.D. Ohio Aug. 19, 2019) (granting motion for summary judgment holding defendants have affirmative duties under the CSA).

Accordingly, it is no surprise that courts have consistently found that the federal issue identified by the Removing Defendant was not “substantial” enough to justify federal jurisdiction. As *Merrell Dow* explained, the absence of a federal cause of action by itself strongly demonstrates the absence of any substantial issue. Moreover, as the court in *Denn* elaborated:

Federal issues must be significant “to the federal system as a whole.” *Gunn*, 568 U.S. at 260. “[I]t is not enough that the federal issue be significant to the particular parties in the immediate suit.” *Id.* . . .

The determination of whether Defendants violated the FCSA is not substantial to the government as a whole. Most importantly, the parties do not seek to interpret the FCSA such that it affects the manner in which the government operates. . . . Rather, the federal issues in this case will be substantial only to the parties. The outcome will not necessarily be dispositive of Plaintiff’s claims and will not be controlling in any other case, as it will involve a factual determination relating to Defendants’ conduct.

2018 WL 1942363, at *4.

The *Balderas* court concurred, adding that the fact that “Plaintiff’s claims will be ‘fact-bound and situation-specific’ and do not readily present a pure issue of law which federal adjudication could resolve ‘once and for all,’” as well as “‘the absence of a private right of action’ under the FCSA” were additional factors that weighed against a finding of substantiality. 323 F. Supp. 3d at 1252. Likewise, the Southern District of West Virginia has twice found the absence of any substantial federal question, reasoning that “[t]he federal courts have little interest in deciding cases involving West Virginia’s Uniform Controlled Substances Act and West Virginia’s negligence and public nuisance law,” holding that this is the case “even if violation of a federal statute or standard is an element of the claims.” *West Virginia*, No. 2:17-cv-03555, ECF No. 21 at 14.⁶

⁶ See also *Granite City*, 2018 WL 3408126, at 2 (“[T]he City’s claims do not raise a larger substantial federal interest, nor do they implicate ‘the action of any federal department, agency, or service.’”); *Weber Cnty.*, 2018 WL 3747846, at *13-14 (agreeing that McKesson’s argument cannot be squared with Supreme Court precedent on this issue); *Uintah Cnty.*, 2018 WL 3747847, at *7 (same); *Cnty. of Anderson*, No. 8:18-cv-01947, ECF No. 44 at 19 (“[T]he federal issue . . . does not rise to the level of federal importance envisioned by *Grable*’s third factor, and is therefore not ‘substantial’ in the way necessary to invoke federal question jurisdiction.”).

In sum, the Removing Defendant's alleged violations of the federal CSA were insufficiently substantial to support federal jurisdiction under *Grable* in more than a dozen other actions and are equally insufficient to support federal jurisdiction here.

iii. Removal of This and Similar Cases Would Disrupt the Federal-State Balance Approved by Congress

Finally, removal of this and similar cases would undoubtedly “disturb[] any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314. In *Grable*, the Supreme Court strongly distinguished between state tort claims based on federal standards (as here) from the narrow (though substantial) tax notice issue it allowed to be removed, holding that:

For if the federal [drug] labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.

One only needed to consider the treatment of federal violations generally in garden variety state tort law. . . . A general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal courts.

545 U.S. at 318-19 (citing *Merrell Dow*, 478 U.S. at 811-12).

Just because the state court here may have occasion to consider the CSA as part of the Government's claims does not change this. As the *Denn* court explained:

Here, much like *Merrell Dow*, entertaining “garden variety” state law tort claims resting on federal statutory violations, such as negligence and fraud, could lead to a flood of state law claims entering federal courts and could disturb congressional intent regarding federal question jurisdiction in § 1331. Considering this potential threat to the structural division of labor between state and federal courts, in addition to the absence of a federal cause of action, it is “improbable that the Congress . . . would have meant to welcome any state-law tort case implicating federal law” merely because the federal statutes create standards of care or elements to causes of action under state law. Thus, the Court cannot entertain Plaintiff's state law

claims without disturbing the congressionally-approved division of labor between federal and state courts.

2018 WL 1942363, at *5 (alteration in original) (quoting in part *Grable*, 545 U.S. at 319); *see also Balderas*, 323 F. Supp. 3d at 1252-53 (quoting and following reasoning in *Denn*); *West Virginia*, No. 2:17-cv-03555, ECF No. 21 (“The federal courts have little interest in exercising jurisdiction over claims alleging violation of state statutory and common law – even where resolution of such claims might involve a ‘federal element’. To do so would shift a significant number of garden-variety state law claims into a federal forum, thereby upsetting the congressionally intended division between state and federal courts.”); *see also, e.g., Great Lakes Gas Transmission Ltd. P’ship v. Essar Steel Minn. LLC*, 843 F.3d 325, 331 (2016). (“[T]he combination of no federal cause of action and no preemption of state remedies’ serves as an ‘important clue’ suggesting a congressionally approved balance *disfavoring* federal involvement.”) (quoting *Grable*, 545 U.S. at 318).

In a case such as this, where removal would invite any claims involving any reference to CSA duties, or duties under other federal statutes, into federal courts across the country, accepting federal jurisdiction “wouldn’t just upset the balance Congress intended to exist between the federal and state judiciaries—it would eliminate it.” *Arnold v. Baxter Healthcare Corp.*, 609 F. Supp. 2d 712, 718 (N.D. Ohio 2009) (applying *Grable* to alleged federal question based on FDA drug regulation); *accord, e.g., DCH Health Care Auth. v. Purdue Pharma L.P.*, CV 19-0756-WS-C, 2019 WL 6493932, at *4–5 (S.D. Ala. Dec. 3, 2019) (“The complaint patently presents no “collateral attack” on the federal government’s controlled substances regime – on the contrary, the complaint applauds that regime while criticizing the defendants for not following it.”)

C. THE GOVERNMENT REQUESTS EXPEDITED CONSIDERATION OF THIS MOTION

As set forth above, the Removing Defendant had no legitimate basis for removing this action to federal court and ignored a large body of authority in doing so. The Government respectfully requests expedited consideration of its remand motion, to avoid needless delay. *See, e.g., Lester E. Cox Med. Centers v. Amneal Pharms., LLC*, 2020 WL 3171452, at *1 (W.D. Mo. June 15, 2020); *Mayor & City Council of Balt. v. Purdue Pharma L.P.*, 2018 WL 1963816, at *3 (D. Md. Apr. 25, 2018); *Great Lakes Gas Transmission Ltd. P'ship v. Essar Steel Minn. LLC*, 843 F.3d 325, 331 (2016).

IV. CONCLUSION

The Government of Puerto Rico respectfully requests an expedited briefing schedule and remand of this action.

Respectfully Submitted this 22nd day of February, 2022.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 22nd day of February 2022, I caused the foregoing *The Government of Puerto Rico's Memorandum of Law in Support of Renewed Motion to Remand and for Expedited Briefing Schedule* to be electronically filed with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF System.

s/Linda Singer
Linda Singer